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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/733,534	12/10/2003	Douglas T. Gjerde	P006.210	7718

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EXAMINER	
MOSS, KERI A	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/733,534	GJERDE ET AL.	
	Examiner	Art Unit	
	KERI A. MOSS	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-28 and 41-53* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-28, 41-53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's Request for Reconsideration filed December 19, 2008 is hereby acknowledged. Claims 14-28, 41-53 are pending.

Response to Amendment

2. After reconsideration, the Examiner has withdrawn the election by original presentation of claims 43-48.

3. Previous objection to claims 19, 22, 43 and 44 has been withdrawn in light of applicant's amendments and arguments.

4. Previous rejection of claims 19, 22, 43 and 44 as indefinite has been withdrawn in light of applicant's amendments and arguments.

5. Previous rejections as anticipated by Agnew et al. and Zimmerman et al. have been maintained.

6. Previous rejections under Zimmerman et al.; or Agnew et al. in view of Zimmerman et al.; either Zimmerman or Agnew in view of Gobom et al.; and Zimmerman in view of Strosberg et al. as obvious have been maintained.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims **14 and 17-18** are rejected under 35 U.S.C. 102(e) as being anticipated by Agnew et al (US Pub 2004/0171034). Agnew et al. teaches a method for extracting a multi-protein complex comprising the steps of introducing a sample solution comprising the multi-protein complex into an extraction channel which has an inner surface comprising an extraction surface that binds the multi-protein complex, passing a wash solution through the channel and passing a first desorption solution through the channel, thereby eluting the first protein (paragraph [0014]).

9. Claims **14, 17-20, 22-24, 26-28, 41-42 and 49-53** are rejected under 35 U.S.C. 102(b) as being anticipated by Zimmerman et al. (USP Re. 32,011). Zimmerman teaches a method for extracting a multi-protein complex comprising the steps of introducing a sample solution comprising the multi-protein complex into an extraction channel which has an inner surface comprising an extraction surface that binds the multi-protein complex, passing a wash solution through the channel and passing a first desorption solution through the channel, thereby eluting the first protein (column 2 line 55-column 3 line 13). The second protein remains adsorbed (column 3 lines 3 lines 3-4). The multi-protein complex comprises a protein antigen (abstract). A second desorption solution is passed through the extraction channel, thereby eluting the second protein (column 8 lines 49-53). The first and second desorption solutions differ

in ionic composition (column 2 line 55-column 3 line 13; column 8 lines 49-53). The first desorption solution inherently contains an agent that effects protein-protein interactions. The desorption solutions are inherently flowed back and forth through the column due to fluid dynamics. The extraction surface is 3-dimensional and is comprised of an affinity binding agent consisting of a protein (column 6 lines 9-36). The method is performed in a plurality of channels operated in parallel or in a solid block having one or more passageways running through (columns 7-8).

Claim Rejections - 35 USC § 103

10. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

11. Claims **15-16 and 43-48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al. or Agnew et al, supra, in view of Gobom et al (Sample Purification and Prepartio technique Based on nano-scale Reversed-phase Columns for the Sensitive Analysis of Complex Peptide Mixtures by Matrix-assisted laser Desorption/Ionization Mass Spectrometry, J. Mass Spectrom., vol 34 pages 105-116 (1999)). Neither Zimmerman nor Agnew expressly teach a capillary extraction channel or purging the extraction channel with a gas prior to passing a desorption solution through the channel wherein the extraction surface remains substantially solvated after the purging step. Gobom et al. teaches a capillary column (Figure 1) comprised of fused silica (p. 107). Gobom teaches that the advantage of using the

capillary column is that it is simple, fast and utilizes only low-cost disposables (abstract). In addition, it allows efficient sample concentration and the elution process yields very small sample spots. Thus, it would have been obvious to modify Zimmerman or Agnew with the capillary column of Gobom in order to gain the advantages of decreasing costs, increasing speed of reaction and making the reaction more efficient. Gobom also teaches using a method of extracting proteins wherein the extraction channel is purged with a gas before adding the desorption solution (page 107, right column). This step this step is imperative for smooth and continuous liquid flow in the next step (abstract, page 107, right column). Thus, it would have been obvious to modify Zimmerman or Agnew by purging the channel with gas before adding the desorption solution in order to gain the predictable results of a smooth and continuous liquid flow during the purification of the protein.

12. Claim **21** is rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al., supra. See Zimmerman supra. Zimmerman does not expressly teach using a third desorption solution to elute a third protein. However, Zimmerman provides all the necessary teaching for eluting more than one protein in a protein complex (column 2 line 55-column 3 line 13; column 8 lines 49-53). It would have been obvious for one of ordinary skill in the art to modify Zimmerman by using a third desorption solution to elute a third protein in order to obtain the predictable results of separating the third protein from the multi-protein complex.

13. Claim **25** is rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al, supra, in view of Agnew et al, supra. Zimmerman does not expressly teach an agent selected from urea, guanidinium chloride and isothiocyanate. Agnew teaches purifying a protein by using an agent comprising reactive groups that bind to phosphate by interfering with protein-protein interactions (paragraphs [0104-0106]). These reactive groups include isothiocyanates and ureas (paragraph [0106]). The advantage of these reactive groups is that they are photoactivatable (paragraph [0154]). The advantage of photoactivatable reactive groups is that the resulting phosphate-binding compound that is useful for conjugation to phosphorylated target molecules (paragraph [0153]). Therefore, it would have been obvious to modify Zimmerman with the reactive groups of Agnew et al. in order to gain the advantages of having a resulting phosphate-binding compound that is useful for conjugation to phosphorylated target molecules.

14. Claims **26-27** are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al., supra, in view of Strosberg et al. (EP 1 178 318 A1). Strosberg teaches using a multi-protein complex that comprises a recombinant bait protein comprising a fusion tag (column 37 line 38- column 39 line 60). Strosberg teaches that these recombinant bait proteins can be used as marker compounds, which have the art-recognized benefit of providing a visible method of determining whether two compounds have interacted. Strosberg also teaches that the benefit of these recombinant bait proteins is that they bind specifically to the polypeptide of interest. Therefore, it would

have been obvious for one of ordinary skill in the art to use a recombinant bait protein with a fusion tag in order to bind to a specific polypeptide of interest and to gain the additional advantages and predictable result of optically determining when that polypeptide has been bound to the recombinant bait protein.

Response to Arguments

15. Applicant's arguments filed December 19, 2008 have been fully considered but they are not persuasive.

16. Applicants argue that none of Agnew, Zimmerman, Gobom or Strosberg teach an extraction channel. It is the duty of the Examiner to apply the broadest reasonable interpretation of the claims. Applicants have cited no portions of the instant specification that define “extraction channel”. A channel is defined by Webster’s II New Riverside Dictionary as “a means of passing, transmitting and communicating.” One of ordinary skill in the art would understand that the term “extraction channel” describes packed bed columns as they are a means of passing or transmitting the components of a sample. All the above references teach an extraction channel as they teach channels that extract a component.

17. Applicants argue that none of Agnew, Zimmerman or Strosberg teach extraction of a multi-protein complex. The examiner respectfully disagrees. It is the duty of the Examiner to apply the broadest reasonable interpretation of the claims. All of these references teach mixtures of proteins from blood or plasma samples. It is well known among those with ordinary skill in the art that the proteins of cells inherently interact,

even when outside the body. Proteins do not stop interacting, even when outside of the cell. This inherency is demonstrated by applicant's own specification in that applicants do nothing to the samples of plasma to cause formation of a multi-protein complex. Electrostatic forces inherently cause interactions between proteins such that they form a complex. Thus, in all of Agnew, Zimmerman or Strosberg, when these references teach extracting proteins from plasma, when the desired protein attaches to the column, there are inherently protein interactions going on that result in that protein attaching to the column while part of a multi-protein complex. Once the protein attaches to the column, it has been extracted. Thus, the above references inherently extract a multi-protein complex.

18. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., open channel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

19. Applicants argue that the references do not teach extraction channel having an inner surface. The examiner disagrees as all packed columns have "inner surfaces" in the form of beads or antibodies that bind to the desired analyte.

20. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., inner periphery of the channel) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification

are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

21. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., gentle treatment of multi-protein complex) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

22. Applicants argue that the motivation to combine Gobom is not found in the references themselves, but has been fabricated by the Examiner. Examiner respectfully disagrees as the Examiner cited sections of Gobom that specifically declare the advantages of the invention.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KERI A. MOSS whose telephone number is (571)272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vickie Kim can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Keri A. Moss/
Examiner, Art Unit 1797

/Vickie Kim/

Supervisory Patent Examiner, Art Unit 4181